



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: May 2, 2018

SUBJECT: **Rimsulfuron:** Human Health Risk Assessment for a Proposed Use on Residential Turf.

PC Code: 129009

Decision No.: 530264

Petition No.: NA

Risk Assessment Type: Single Chemical Aggregate Risk Assessment

TXR No.: NA

MRID No.: NA

DP Barcode: D440913

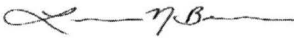
Registration No.: 53883-307

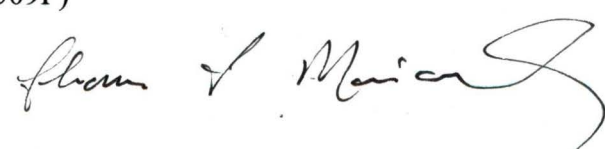
Regulatory Action: Section 3 Registration

Case No.: NA

CAS No.: 122931-48-0

40 CFR: §180.478

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The Registration Division (RD) of the Office of Pesticide Programs (OPP) has requested that the Health Effects Division (HED) evaluate the new use of rimsulfuron on turf in residential areas for the active ingredient (ai), rimsulfuron. A summary of the findings and an assessment of human health risks resulting from the proposed and registered uses of rimsulfuron are provided in this document. The most recent human health risk assessment for rimsulfuron was performed in 2018 (R. McGovern, D435771, 01/03/2018).

1.0 Introduction

Rimsulfuron (N-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide) is a systemic herbicide belonging to the sulfonylurea group and is used for pre- and post-emergent control of annual grasses, broadleaf weeds, and yellow nutsedge. It is registered for use on agricultural and non-cropland areas (e.g., commercial turf, rangeland).

Control Solutions Inc. has submitted a petition for the active ingredient (ai), rimsulfuron, in order to add a new use on turf in residential areas for Quali-Pro® Negate™ 37WG (EPA Reg. No. 53883-307); a water dispersible granule (WDG) end-use product that contains 16.67% rimsulfuron by weight and 20% metsulfuron-methyl by weight. This assessment considers exposures from rimsulfuron only. The label specifies a maximum single application rate of 1.5 oz product/acre (A) (0.016 lb ai/A). This product directs applicators and other handlers to wear a long-sleeved shirt and long pants; shoes and socks; and chemical-resistant gloves. The restricted entry interval (REI) listed on the end-use product label is 4 hours.

Exposure to rimsulfuron may occur from dietary (food and drinking water), occupational, and non-occupational/residential sources. For the proposed use of rimsulfuron on residential turf, additional exposures from food or drinking water are not anticipated. The proposed use may result in non-occupational/residential and occupational exposures.

The subject risk assessment assesses the exposures and risks from the proposed use of rimsulfuron on residential turf. The last completed risk assessment of rimsulfuron was in 2018 (R. McGovern, D435771, 01/03/2018). Since the time of that assessment, there have been no changes to the hazard characterization or hazard profile or the Food Quality Protection Act (FQPA) safety factors. Additionally, there have been no updates to the residue chemistry database and the dietary (food + water), and non-occupational spray drift exposure and risk assessments for rimsulfuron remain current and unchanged. The occupational exposures and risk estimates for the currently proposed use pattern were previously quantified in the ORE assessment for applications of rimsulfuron to turf in non-residential areas (i.e., golf courses, sod farms, professionally managed college and professional sports fields, industrial and commercial lawns, and other similar non-residential areas), at the same application rate and with the same use directions and limitations as is currently being proposed for residential turf use. Further information, including occupational handler risk estimates, may be found in the draft risk assessment for registration review of rimsulfuron (M. Mercado-Feliciano, D425703, 09/14/2015). There were no risk estimates of concern identified in that assessment. Thus, the scope of this risk assessment includes: a residential exposure and risk assessment; and a short-term aggregate risk assessment for children 1 to <2 years old.

Residential Exposures

Post-application incidental oral exposures are anticipated from the proposed use of rimsulfuron on residential lawns and turf. There is also the potential for post-application dermal exposures to rimsulfuron for adults and other lifestyles; however, because no dermal hazard was identified in the rimsulfuron database, a residential post-application dermal exposure assessment has not been conducted. Inhalation exposures are not anticipated based on the use pattern. The incidental oral risk estimates quantified in this assessment are not of concern.

Aggregate Exposures

The recommended residential exposure for use in the aggregate assessment is short-term incidental oral hand-to-mouth exposures to children 1 to <2 years old following applications to residential lawns or turf. When combined with background dietary (food + drinking water) exposures, this resulting short-term aggregate margin of exposure (MOE) is not of concern. For all other age groups, the aggregate assessments are equivalent to the dietary (food + drinking water) assessments, and are not of concern.

Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.”¹

Human Studies Review

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include the Residential SOPs (Turf/Lawn and Gardens/Trees) are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency website².

2.0 HED Conclusions

HED has examined the toxicology, residue chemistry, dietary and non-dietary exposure databases for rimsulfuron. Other than as described in Section 3.0, HED concludes that the recently-completed risk assessment for rimsulfuron is adequate to account for the potential exposure and risk estimates for the proposed use on residential turf (R. McGovern, D435771, 01/03/2018). HED has no concerns that would preclude granting the new use and Section 3 registration associated with this action.

¹ <https://www.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice>

² <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data> and <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-post-application-exposure>

3.0 Detailed Considerations

Proposed Use Profile

Table 3.0.1. Summary of Proposed Directions for Use of Rimsulfuron.						
Applic. Timing, Type, and Equip.	Trade Name; Formulation [EPA Reg. No.]	Max. Single Application Rate	Max. No. Applic. per Year	Max. Annual Applic. Rate	PHI ¹ (days)	Use Directions and Limitations ¹
Residential Turf/Lawns						
Pre- or post-emergence broadcast or chemigation	Pruvin®; water-dispersible granule (16.67% ai) [53883-307]	1.5 oz product/Acre (0.016 lb ai/A)	4	6 oz product/A/yr (0.063 lb ai/A/yr)	NA	Mixed end-use product with metsulfuron-methyl; use 20-80 spray volume GPA; do not apply this product by air.

¹ PHI= pre-harvest interval

² GPA= gallons per acre

Toxicological Points of Departure (PODs) Used for Risk Assessment

No new toxicity data have been submitted since the last risk assessment, and the endpoints and PODs remain unchanged (R. McGovern, D435771, 01/03/2018). The endpoints and PODs for rimsulfuron are provided below:

Table 3.0.2. Summary of Toxicity Endpoints and Points of Departure for Rimsulfuron for Use in Human Health Risk Assessment.				
Exposure Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary: All populations	An endpoint attributable to a single dose was not identified in the database.			
Chronic Dietary: All populations	NOAEL= 11.8 mg/kg/day	UF _A = 10X UF _H = 10X FQPA SF = 1X	Chronic RfD = 0.118 mg/kg/day cPAD = 0.118 mg/kg/day	Combined Chronic/ Carcinogenicity – Rat LOAEL = 121 mg/kg/day based on decreased body weight gains and liver effects.
Inhalation Exposure: Short-Term	NOAEL= 6.25 mg/kg /day <i>Inhalation toxicity assumed to be equivalent to oral toxicity.</i>	UF _A = 10X UF _H = 10X FQPA SF = 1X	Residential LOC for MOE = 100	90-day toxicity study – Dog LOAEL = 125 mg/kg/day based on increased urinary volume, kidney weights, and decreased osmolality.

Table 3.0.2. Summary of Toxicity Endpoints and Points of Departure for Rimsulfuron for Use in Human Health Risk Assessment.

Exposure Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental Oral: Short-Term	NOAEL= 6.25 mg/kg /day	UF _A = 10 UF _H = 10 FQPA SF = 1X	Residential LOC for MOE = 100	90-day toxicity study – Dog LOAEL = 125 mg/kg/day based on increased urinary volume, kidney weights, and decreased osmolality.
Dermal Exposure: Short-Term	A dermal endpoint was not selected because rimsulfuron is not expected to be toxic through the dermal route.			
Cancer (oral, dermal, inhalation)	Not a carcinogen based on the lack of evidence of carcinogenicity in rats and mice.			

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, MOE = margin of exposure, LOC = level of concern, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose. FQPA SF = Food Quality Protection Act safety factor; UF_A = uncertainty factor for inter-species variation; UF_H = uncertainty factor for inter-species variations. POD = point of departure.

Residential Exposure and Risk Estimates

Residential Handler Exposure Data and Assumptions

The end-use product requesting the addition of turf in residential use sites (e.g., residential turf or lawns) require that handlers wear specific clothing (e.g., long-sleeve shirt/long pants) and use personal protective equipment (PPE) (i.e., chemical-resistant gloves). Therefore, HED has made the assumption that these products are not for homeowner use, and has not conducted a quantitative residential handler assessment.

Residential Post-Application Exposure Data and Assumptions

There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with rimsulfuron. The quantitative exposure and risk assessment for residential post-application exposures is based on the proposed use on residential turf or lawns.

A series of assumptions and exposure factors served as the basis for completing the residential post-application risk assessment. Each assumption and factor is detailed in the occupational and residential exposure assessment associated with this action (L. Bacon, D446031, 03/16/2018). The algorithms used to estimate residential post-application exposure and dose can be found in the 2012 Residential SOPs³.

Summary of Residential Post-Application Non-Cancer Exposure and Risk Estimates

The residential post-application risk estimates reflect incidental oral exposures to children 1 to <2 years old. Incidental oral scenarios (i.e., hand-to-mouth and object-to-mouth) should be considered inter-related and it is likely that they occur interspersed amongst each other across time. Post-application inhalation exposures are not anticipated based on the proposed use site.

³ <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>

While there is the potential for dermal exposures from treated residential turf, the dermal route of exposure has not been assessed because there is no adverse systemic hazard resulting from dermal exposures to rimsulfuron.

Table 3.0.3. presents the residential post-application risks following the use of rimsulfuron on residential turf. The recommended residential exposure for use in the children 1 to <2 years old short-term aggregate assessment is hand-to-mouth post-application exposure to turf treated with rimsulfuron.

Table 3.0.3. Residential Post-application Incidental Oral Exposure and Risk Estimates for Rimsulfuron.					
Lifestage	Post-application Exposure Scenario		Application Rate¹	Dose (mg/kg/day)²	MOEs³
	Use Site	Route of Exposure			
Children 1 to <2 years old	Residential turf/lawns	Hand-to-Mouth	0.016	0.0002	26,000
		Object-to-Mouth		0.00001	840,000
		Soil Ingestion		5.4E-07	12,000,000

1 Based on registered or proposed label (Reg. No. 53883-307).

2 Dose (mg/kg/day) algorithms provided in 2012 Residential SOPs (<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>).

3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day).

Data Deficiencies and Requirements

In accordance with 40 CFR 158, turf transferrable residue (TTR) data are required for all occupational (e.g., sod farms, golf courses, parks, and recreational areas) or residential turf uses that could result in post-application exposure to turf. In the absence of chemical-specific TTR data, EPA uses default values. In association with the current action, the registrant submitted a waiver request from the requirement to conduct a TTR study. While there is the potential for post-application dermal exposures to rimsulfuron based upon the use pattern, there is no adverse systemic hazard resulting from dermal exposures to rimsulfuron. Furthermore, although there is also potential for incidental oral exposure, the estimated residential turf post-application exposure using default TTR values for rimsulfuron is minimal in comparison to the level of concern (i.e., the lowest calculated MOE is greater than 10 times higher than the level of concern, MOE = 26,000 compared to the LOC of 100). Therefore, HED is granting the waiver request from the requirement of the TTR study. In the future, additional data on turf transferable residues may be required in case refinement of exposure assessments is needed and/or to further EPA's general understanding of the availability of pesticide residues on turf.

Dietary (Food + Water) and Aggregate Exposure and Risk Estimates

HED is required to assess and aggregate (add) exposures from three sources when conducting a human health risk assessment; food, drinking water, and residential exposures. The proposed use of rimsulfuron on residential turf will not result in additional dietary (food + drinking water) exposures to this compound. For the assessment of risk from residues of rimsulfuron, residential exposures are expected only for children 1 to <2 years old.

The aggregate exposures and risks are equivalent to the dietary (food + drinking water) exposures and risk estimates for all subpopulations, other than children 1 to 2 years old, and are detailed in the last completed risk assessment for rimsulfuron; those estimates were not of concern (R. McGovern, D435771, 01/03/2018). For the current action, the short-term aggregate risk assessment quantified potential residential post-application exposures (Table 3.0.3)

combined with the previously-quantified average dietary (food and drinking water) exposure for children 1-2 years old of 0.001676 mg/kg/day (R. McGovern, D435771, 01/03/2018). The resulting short-term aggregate risks are calculated in Table 3.0.4, below. The short-term aggregate exposure estimate resulted in an MOE greater than the LOC of 100, and is not of concern.

Table 3.0.4. Short-Term Aggregate Risk Calculations							
Population	Short-Term Scenario						
	NOAEL mg/kg/day	LOC¹	Max Allowable Exposure² mg/kg/day	Average Food and Water Exposure mg/kg/day	Residential Exposure mg/kg/day³	Total Exposure mg/kg/day⁴	Aggregate MOE (food, water, and residential)⁵
Children 1-2 years old	11.8	100	0.118	0.001675	0.0002	0.001875	6,300

¹ The LOC = 100 and includes the standard inter- and intra-species uncertainty factors (10x UFA and 10x UFH, respectively) and reduction of FQPA SF to 1x

² Maximum Allowable Exposure (mg/kg/day) = NOAEL of 11.8 mg/kg/day/LOC of 100.

³ Residential Exposure = [Oral Exposure] from Table 3.2.

⁴ Total Exposure = Avg Food & Water Exposure + Residential Exposure.

⁵ Aggregate MOE = [NOAEL ÷ (Avg Food & Water Exposure + Residential Exposure)].

Non-Occupational Spray Drift Exposure and Risk Estimates

The potential for spray drift was previously quantitatively evaluated for rimsulfuron during the registration review process; incidental oral risk estimates from drift onto residential areas were evaluated for rimsulfuron using maximum registered application rates. Further information may be found in the draft risk assessment for the registration review of rimsulfuron (M. Mercado-Feliciano, D425703, 09/14/2015). This current action is not expected to result in increased spray drift potential exposures.

Occupational Exposure and Risk Estimates

The occupational exposures and risk estimates for the currently proposed use pattern were previously quantified in the ORE assessment for applications to turf in non-residential areas (i.e., golf courses, sod farms, professionally managed college and professional sports fields, industrial and commercial lawns, and other similar non-residential areas), at the same application rate and with the same use directions and limitations. The occupational handler inhalation MOEs ranged from 5,100 to 9,400,000 (LOC = 100) and the occupational post-application assessment did not quantify MOEs because no hazard via the dermal pathway is anticipated. Further information, including occupational handler risk estimates, may be found in the draft risk assessment for registration review of rimsulfuron (M. Mercado-Feliciano, D425703, 09/14/2015). There were no risk estimates of concern identified in the assessment.

4.0 References

Bacon, L., D446031, 03/16//2018. Rimsulfuron. Occupational and Residential Exposure Assessment for New Use on Residential Turf.

McGovern, R., D435771, 01/03/2018. Rimsulfuron. Human Health Risk Assessment in Support of a Petition (PP#6E8496) for the Establishment of Permanent Tolerances on Tuberous and

Corn Vegetable Subgroup 1 C, Small Vine Climbing Fruit Except Fuzzy Kiwifruit Subgroup 13-07F, Low Growing Berry Except Strawberry Subgroup 13-07H, Tolerances with Regional Registrations for Ryegrass and Fescue and Crop Group Conversions for Citrus Fruit Group 10-10, Pome Fruit Group 11-10, Stone Fruit Group 12-12, and Tree Nut Group 14-12.

Mercado-Feliciano, M., D425703, 09/14/2015. Rimsulfuron. Human Health Draft Risk Assessment for Registration Review.